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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/516,598	12/03/2004	Jun Kubota	389.44528X00	8546

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EXAMINER	
TALMAN, JAMES R	
ART UNIT	**PAPER NUMBER**
3709	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/516,598	KUBOTA ET AL.	
	Examiner	Art Unit	
	James R. Talman	3709	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 December 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *12/3/2004* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. 10516598.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Specification

1. The disclosure is objected to because of the following informalities:

On page 1, line 25, "diagnoses" should be changed to –diagnose--.

On page 2, line 3, "modules" should be changed to –modulus--.

On page 2, line 6, "applied a body" should be changed to –applied to a body--.

On page 2, line 14, "said the probe" should be changed to –said probe--.

On page 3, line 19, "so as to the displacements can be relatively observed" should be changed to –so that the relative displacements can be observed--.

On page 4, line 4, "filtered" should be changed to –filtering--.

On page 7, line 4, "produced" should be changed to –produces--.

On page 7, line 13, "display" should be changed to –displays--.

On page 8, line 8, "signals acquired" should be changed to –signals is acquired--.

On page 9, line 13, "so as to" should be changed to –so that--.

On page 10, line 15, "so at to" should be changed to –so that--.

On page 11, line 4, "ware" should be changed to –were--.

On page 14, line 19, "display of" should be changed to –display--.

On page 16, line 9, "4a" should be changed to –14a--.

On page 17, line 7, "Wherein, the" should be changed to –The--.

On page 18, lines 3-5, "Consequently, the time required for examination will become even despite a difference in experience in ultrasonic examination" should be changed to –Consequently, the examination time will be shortened--.

Drawings

2. The drawings are objected to because of the following minor informalities:

On Figure 1, element 1, "Prove" should be changed to –Probe--.

On Figure 1, element 2, "transmittting" should be changed to –transmitting--.

On Figure 3, "filtered" should be changed to –filtering--.

On Figure 8, element 16, "article" should be changed to –arithmetic--.

On Figure 15, element 152, "reagion" should be changed to –region--.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Appropriate correction is required.

Claim Objections

1. Claim 8 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 1-6, 8, and 11-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Miwa et al (JP 2000060857) in view of Ophir et al (Elastographic Imaging, Ultrasound in Medicine and Biology, Vol 26, supplement 1, pp. S23-S29, 2000).

As per claims 1-4, and 8, Miwa et al discloses an ultrasound probe (31), a first image production means (tomogram, see abstract), an image display (display part 4; see also Figure 5a), at least one piece of reference information (13), a second image (Figure 5b), and a variation operation (2ΔL, see Figure 5b). Miwa et al does not explicitly disclose a distortion operation or displaying of distortion information. Ophir et

al discloses a distortion operation (local axial strain, p. S27, column 1, Equation 1), based on the comparison of a locus of points in a region of interest (temporal windows, p. S27, column 1) in the two images, and display of distortion information (Figures 1-4). It would have been obvious to a person having ordinary skill in the art at the time of the invention to modify Miwa et al to include a distortion operation and display of distortion information because the latter information allows the detection of cancerous tumors and/or lesions that are stiffer than their surroundings and are either too small, or not echogenic enough, or too deep, to be detected by conventional B-scan ultrasound or palpation techniques. The above motivation to combine is taught by Ophir et al (p. S23, column 1).

As per claim 5, Miwa et al does not disclose displaying distortion information at the deepest part of the image. Ophir et al further discloses displaying distortion information at the deepest part of the image (bottom of Figure 3). It would have been obvious to a person having ordinary skill in the art at the time of the invention to use the method of Miwa et al to display the distortion information at the deepest part of the image because palpation is least effective at detecting tumors and/or lesions at larger depths.

As per claim 6, Miwa et al further discloses automatically determining appropriate imaging parameters (automatic judging of the hardness, p. 7, line 10), at a predetermined portion (organization, p. 7, line 10) of the image.

As per claim 11, 12, 13, 14, Miwa et al discloses an method of ultrasonic imaging comprising an ultrasound probe (31), a first image production means (tomogram, see

abstract) using said probe in contact a subject in a first state (before pressurization, see abstract), an image display (display part 4; see also Figure 5a), at least one piece of reference information (13), a second image (Figure 5b) obtained by bringing said probe into contact with a subject in a second state different from said first state (after pressurization, see abstract), and a variation operation (2ΔL, see Figure 5b). Miwa et al does not explicitly disclose a distortion operation or displaying of distortion information. Ophir et al discloses a distortion operation (local axial strain, p. S27, column 1, Equation 1), based on the comparison of a locus of points in a region of interest (temporal windows, p. S27, column 1) in the two images, and display of distortion information (Figures 1-4). It would have been obvious to a person having ordinary skill in the art at the time of the invention to modify Miwa et al to include a distortion operation and display of distortion information because the latter information allows the detection of cancerous tumors and/or lesions that are stiffer (i.e. undergo less strain) than their surroundings and are either too small, or not echogenic enough, or too deep, to be detected by conventional B-scan ultrasound or palpation techniques. The above motivation to combine is taught by Ophir et al (p. S23, column 1).

As per claim 15, Miwa et al does not disclose displaying distortion information at the deepest part of the image. Ophir et al further discloses displaying distortion information at the deepest part of the image (bottom of Figure 3). It would have been obvious to a person having ordinary skill in the art at the time of the invention to use the method of Miwa et al to display the distortion information at the deepest part of the

image because palpation is least effective at detecting tumors and/or lesions at larger depths.

As per claim 16, Miwa et al further discloses automatically determining appropriate imaging parameters (automatic judging of the hardness, p. 7, line 10), at a predetermined portion (organization, p. 7, line 10) of the image.

4. Claims 7 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Miwa et al (JP 2000060857) in view of Ophir et al (Elastographic Imaging, Ultrasound in Medicine and Biology, Vol 26, supplement 1, pp. S23-S29, 2000) as applied to claim 1 above, and further in view of Chen et al (US 7050610).

The Miwa et al/Ophir et al combination as applied to claims 1 and 11 above discloses all the elements of the claimed invention except that it does not explicitly disclose displaying a different color or shape. Chen et al discloses color scale imaging in the context of strain imaging (column 1, lines 21-22). It would have been obvious to a person having ordinary skill in the art at the time of the invention to modify the Miwa et al/Ophir et al combination to use a color display as taught by Chen et al in order to obtain a clearer visualization of the strain field, as is well known in the art.

5. Claims 9 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Miwa et al (JP 2000060857) in view of Ophir et al (Elastographic Imaging, Ultrasound in Medicine and Biology, Vol 26, supplement 1, pp. S23-S29, 2000) as applied to claim 1 above, and further in view of Yamashita et al (Ultrasonic Characterization of Tissue Hardness in the in-vivo Human Liver, 1994 IEEE Ultrasonics Symposium, 1449-1453).

The Miwa et al/Ophir et al combination as applied to claim 1 above discloses all the elements of the claimed invention except that it does not explicitly disclose calculating or graphing tissue displacement. Yamashita et al discloses calculating and graphing the distribution of tissue displacement (Figure 2c; see also abstract) as well as character strings indicating the displacement values (Figure 2c). Yamashita et al and Miwa et al are analogous art because both are in the field of ultrasonic elastography. It would have been obvious to a person having ordinary skill in the art at the time of the invention to include the graph of tissue displacement with the invention of Miwa et al because the displacement information is used to calculate the strain information. Displaying the displacement information gives an additional perspective to the tissue parameters to that provided by the strain distribution and, furthermore, the displacement information can be used as a check on the strain display to indicate possible errors or inaccuracies or ranges of validity in the latter. For example, in Figure 5c of Yamashita et al, the strain calculation will clearly not be valid for horizontal distances less than approximately 10 mm or greater than approximately 65 mm because of the abrupt changes in displacement at those points.

Conclusion

6. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Patent literature

US 6494840, Mak et al. Ultrasonic palpation.

US5606971, Sarvazyan. Shear wave elasticity imaging.

US5524636, Sarvazyan et al. Distortion relative to reference position.

US5265612, Sarvazyan et al. Catheter, pressure applied by fluid.

US5678565, Sarvazyan. Pressure sensing array.

US6099471, Torp et al. Ultrasonic strain-rate imaging.

Non-patent literature

"Imaging of the Elastic Properties of Tissue – A Review", Ultrasound in Medicine and Biology, Gao, L. et al, Vol. 22, No. 8, pp.954-977, 1996.

"Ultrasonic Imaging of Elasticity of Soft Tissue Based on Measurement of Internal Displacement and Strain," Yamashita, Y. et al, 1995 IEEE Ultrasonics Symposium, pp. 1207-1211.

"Internal Displacement and Strain Imaging Using Ultrasonic Speckle Tracking," O'Donnell et al, IEEE Transactions on Ultrasonics, Ferroelectrics, and Frequency Control, Vol. 41, No. 3, May, 1994.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James R. Talman whose telephone number is 571-270-3029. The examiner can normally be reached on 7:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynda Jasmin can be reached on 571-270-3033. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

James R Talman
Examiner
Art Unit 3709

jrt

BENNY TIEU
PRIMARY EXAMINER